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10/085,355	02/28/2002	Robert Portman	TBA	8462

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EXAMINER

KAM, CHIH MIN

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 04/29/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/085,355

Applicant(s)

PORTMAN, ROBERT

Examiner

Chih-Min Kam

Art Unit

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-21 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-21 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. ____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------------------------------------------------------------|----------------------------------------------------------------------------------------|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>2/13/04</u> . | 6) <input type="checkbox"/> Other: ____ |

DETAILED ACTION

Status of the Claims

1. Claims 1-21 are pending.

Applicants' amendment filed February 13, 2004 is acknowledged, and applicants' response has been fully considered. Claims 1-21 have been amended. Thus, claims 1-21 are examined.

Objection Withdrawn

2. The previous objection to the specification regarding Fig. 4 and Fig. 5 is withdrawn in view of applicants' amendment to the specification, and applicants' response at page 7 in the amendment filed February 13, 2004.

3. The previous objection to claims 2-13 and 15-21 is withdrawn in view of applicants' amendment of the claim in the amendment filed February 13, 2004.

Rejection Withdrawn

Claim Rejections - 35 USC § 112

4. The previous rejection of claims 1-21 under 35 U.S.C.112, second paragraph regarding the term "CCK", "whey, soy", "calcium citrate maleate", "water soluble, natural or artificial, extracts of apple....", "water soluble, natural or artificial, dyes of blue....", antecedent basis, or whether part (a) of protein includes part (c) of proteinase inhibitor, is withdrawn in view of applicants' amendment to the claim, and applicants' response at pages 7-9 in the amendment filed February 13, 2004.

Claim Rejections-Obviousness Type Double Patenting

5. The previous rejection of claims 1, 2 and 4-13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 6, 7, 9-12, 17, 20 and 23-26 of U. S. Patent 6,436,899 in view of Phillips *et al.* (U. S. Patent 5,468,727), is withdrawn in view of applicants' response at pages 12-14 in the amendment filed February 13, 2004.

6. The previous rejection of claims 1, 4-11, 14, 15, 17 and 19-21 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 10, 12, 13, 18, 26, 27, 29, 30 and 37 of U. S. Patent 6,429,190 in view of Phillips *et al.* (U. S. Patent 5,468,727), is withdrawn in view of applicants' response at pages 12-14 in the amendment filed February 13, 2004.

7. The previous rejection of claims 1, 2, 4-10, 12 and 13 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 53, 60, 61, 63, 71-72, 75, 82, 85, 87, 92, 93, 95 and 97 of copending application 10/211,676 (now U. S. Patent 6,429,190) in view of Phillips *et al.* (U. S. Patent 5,468,727), is withdrawn in view of applicants' response at pages 12-14 in the amendment filed February 13, 2004.

In response, applicants indicate in the third rejection, copending application 09/817,943 instead of 10/211,676 (recently issued as U. S. Patent 6,716,815) is mentioned. As indicated by the applicant at page 12 of the response, this is not Examiner's intention to use it for the rejection because 09/817,943 has been abandoned. Please see MPEP 804 regarding obviousness-type double patenting. The criterion for the obviousness-type double patenting rejection is whether the instant application and the potentially conflicting application or patent has a common inventor or assignee, the effective filing date of the instant application which is before or after

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the filing date of potentially conflicting application or patent would determine one-way or two-way test applies. The citation of a secondary reference in a combination with a potentially conflicting application or patent is permissible in the obviousness-type double patenting rejection.

Claim Objection

8. Claim 11 is objected to because of the use the term “comprising water soluble, natural or artificial, dyes”. The comma “,” between artificial and dyes should be deleted.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

9. Claims 1-21 remain rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for a nutritional intervention composition in a dry powder for extending post meal satiety comprising casein, whey or soy protein that stimulates cholecystokinin (CCK) release, oleic acid or a C12-C18 fatty acid, calcium and a proteinase inhibitor from potato, POT II within specific percentage range; and a method of extending post meal satiety and decreasing post meal hunger in a human by administering to the human prior to the meal a drink containing the composition, does not reasonably provide enablement for a nutritional intervention composition in a dry powder form for extending post meal satiety comprising a protein that stimulates CCK release, a long chain fatty acid, calcium and a proteinase inhibitor from a plant extract within specific percentage range; or a method of extending post meal satiety and decreasing post meal hunger in a human by administering to the

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human prior to the meal a drink containing the composition, where the protein and the proteinase inhibitor in the composition are not identified. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

Claims 1-21 encompass a nutritional intervention composition in a dry powder for extending post meal satiety comprising a protein that stimulates CCK release, a long chain fatty acid, calcium and a proteinase inhibitor from a plant extract within specific percentage range (claims 1-13), and a method of extending post meal satiety and decreasing post meal hunger in a human by administering to the human prior to the meal a drink containing the composition (claims 14-21). The specification, however, only discloses cursory conclusions (page 5, lines 2-9), which states that a nutritional intervention composition in a dry powder, comprising a protein, a long chain fatty acid, calcium and a proteinase inhibitor within specific percentage range is taken prior to a meal and extends post meal satiety in a fashion that is efficient in terms of added calories. There are no indicia that the present application enables the full scope in view of a nutritional intervention composition in extending post meal satiety as discussed in the stated rejection. The present application does not provide sufficient teaching as to how the full scope of the claims is enabled. The factors considered in determining whether undue experimentation is required, are summarized in In re Wands (858 F2d at 731,737, 8 USPQ2d at 1400,1404 (Fed. Cir.1988)). The factors most relevant to this rejection are the breadth of the claims, the presence or absence of working examples, the state of the prior art and relative skill of those in the art, the predictability or unpredictability of the art, the nature of the art, the amount of direction or guidance presented, and the amount of experimentation necessary.

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(1). The breadth of the claims:

The breadth of the claims is broad and encompasses unspecified variants regarding the proteins that stimulate CCK release and the proteinase inhibitors from plant extract in the nutritional intervention composition, which are not adequately described or demonstrated in the specification.

(2). The presence or absence of working examples:

The specification demonstrates a nutritional intervention composition comprising a whey protein, oleic acid or C12-C18 fatty acid, calcium and a proteinase inhibitor from potato, POT 2, and the use of the composition prior to a meal reduced hunger and extended satiety following the meal (Experiments 1-2). There are no other working examples indicating the variants in association with the claimed methods.

(3). The state of the prior art and relative skill of those in the art:

The related art (e.g., Phillips *et al.*, U. S. Patent 5,468,727) disclose Proteinase Inhibitor II (POT II) from potato is an effective gastric emptying inhibiting substance, and a drink composition for studying gastric emptying contains POT II extract from potato; Hill et al. (Physiology & behavior Vol. 48, pages 241-246, 1990) teach POT II increases CCK release and oral administration of POT II reduces energy intake in man, as well as dietary protein is a stimulus for CCK release. However, the general knowledge and level of the skill in the art do not supplement the omitted description, the specification needs to provide specific guidance on identities of various proteins and proteinase inhibitors, and the effects of the composition containing these proteins and protein inhibitors to be considered enabling for variants.

(4). Predictability or unpredictability of the art:

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The claims encompass compositions containing various proteins that stimulate CCK release, and proteinase inhibitors, however, the identities of these proteins and proteinase inhibitors, and the effects of proteinase inhibitors in inactivating chymotrypsin and trypsin are not described in the specification, the invention is highly unpredictable regarding the outcome of the claimed method.

(5). The amount of direction or guidance presented and the quantity of experimentation necessary.

The claims are directed to a nutritional intervention composition for extending post meal satiety comprising a protein that stimulates CCK release, a long chain fatty acid, calcium and a proteinase inhibitor within specific percentage range, and a method of extending post meal satiety and decreasing post meal hunger in a human by administering to the human prior to the meal a drink containing the composition. The specification demonstrates a nutritional intervention composition including a whey protein, oleic acid or a C12-C18 fatty acid, calcium and a proteinase inhibitor from potato, POT II having specific percentage range, which can extend post meal satiety and decrease post meal hunger (Experiments 1 and 2), it also indicates both trypsin and chymotrypsin are involved in inactivating CCK releasing protein (CCKRP), where CCKRP stimulates CCK release from intestinal cells, it appears that chymotrypsin plays a more important role in inhibiting CCK release, thus, the nutritional intervention composition of the present invention including proteinase inhibitors from potato, soy or beans that block trypsin as well as chymotrypsin would provide more effective CCK release in human (page 5, lines 10-13). However, the specification has not demonstrated the use of nutritional intervention compositions containing various proteins that stimulate CCK release and various proteinase

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inhibitors in extending meal satiety and decreasing post meal hunger, nor has shown the effects of these compositions. Since the specification does not provide sufficient teachings on the identities of various proteins and proteinase inhibitors, and the use of various proteins and various proteinase inhibitors in the composition for extending meal satiety, it would require additional guidance to carry out further experimentation to assess the effect of the composition containing various proteins that would stimulate CCK release and proteinase inhibitors in extending meal satiety.

(6). Nature of the Invention

The scope of the claims is directed to compositions containing various proteins that stimulate CCK release and various proteinase inhibitors, and a method of extending meal satiety using the composition, however, the specification has not provided sufficient teachings on identities of various proteins that stimulate CCK release and the effects of proteinase inhibitors, nor has demonstrated the effects of these variants in the composition. Thus, the disclosure is not enabling for reasons discussed above.

In summary, the scope of the claim is broad, while the working example does not sufficiently demonstrate the claimed variants and the methods associated with variants, the effects of the composition containing variants are unpredictable and the teachings in the specification are limited, therefore, it is necessary to have additional guidance and to carry out further experimentation to assess the effects of various nutritional intervention compositions in extending meal satiety.

In response, applicants indicate the claims are limited to compositions containing ingredients that stimulate CCK release, and the experiment required to determine whether a

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given protein will stimulate the release of CCK is clearly within the skill of the art; the specification has given examples of representative substances for each of the components of the claimed composition and methods, and the claims are limited to only those members of the appropriate class of substances that are efficacious in stimulating CCK release; the level of skill in the art is high, and the one skilled in the art has been aware of proteins and proteinase inhibitors that stimulate CCK release; the Examiner has not challenged the predictability of whether protein and proteinase inhibitors that do stimulate the release of CCK will be effective in the claimed compositions and methods; no basis has been established that one of ordinary skill in the art would have reason to doubt other compositions prepared according to the details given in the specification utilizing components possessing the ability to stimulate the release of CCK and a proteinase inhibitor that blocks trypsin and chymotrypsin would be effective in the claimed method; and since the claimed composition are limited to components that are effective in the release of CCK, and a proteinase inhibitor that is known to inactivate trypsin and chymotrypsin, thus some experimentation may be required to achieve optimum results with a given composition, however such experimentation is respectively to be routine. Applicant has asserted the current pending claims are fully enabled by the specification and do not require undue experimentation based on the reasoning to the factors presented in *In re Wands* (pages 9-12 of the response). The response has been fully considered, however, the argument is not found persuasive because the specification only demonstrates a specific nutritional intervention composition comprising a whey protein, oleic acid or C12-C18 fatty acid, calcium and a proteinase inhibitor from potato, POT 2, and the use of the composition prior to a meal reduced hunger and extended satiety following the meal, it does not disclose various compositions

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comprising various proteins that stimulate CCK release, various fatty acids, and various proteinase inhibitors, which are encompassed by the claims. Since various proteins and protein inhibitors are not identified and sufficiently described for the claimed composition, and one skilled in the art would not know how to use make/use the claimed composition. Moreover, the claimed method encompasses the use of unspecified proteinase inhibitors in the composition, where the structures and the effects of the proteinase inhibitors are not described in the specification, thus it requires undue experimentation to identify the proteinase inhibitors that inactivate trypsin and chymotrypsin, and to assess the effect of the composition containing the proteins that stimulate CCK release and the proteinase inhibitors.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

10. Claims 4 and 13-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

11. Claim 4 is indefinite because the claim recites the protein comprises a mixture of essential amino acids, while a mixture of essential amino acids is not a protein.

In response, applicants indicate the specification cites the protein component of the subject compositions may be a mixture of essential amino acids, upon which the definiteness of the term is to be judged (pages 7-8 of the response). The response has been fully considered, however, the argument is not found persuasive because the protein may be made of essential

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amino acids which are connected via amide bonds to form a protein. A mixture of essential amino acids, which are covalently bonded, is not a protein.

12. Claim 13 is indefinite because the claim which claim 13 is dependent from is not identified.

13. Claims 14-21 are indefinite because the claim lacks essential steps in the method of extending post meal satiety and decreasing post meal hunger in a human. The omitted step is the outcome of the process. Claims 15-21 are included in the rejection because they are dependent on rejected claims and do not correct the deficiency of the claim from which they depend.

In response, applicants indicate the claim clearly recites the object of the method as extending post meal satiety and decreasing post meal hunger, which is the outcome; and there are thousands of process claims in patents directed to methods of achieving a multitude of medical and pharmaceutical objects that recites no more than “a method of treating, for example hypertension” without stating an “outcome” (page 9 of the response). The response has been fully considered, however, the argument is not found persuasive because the claim only cites the object of the method without indicating the endpoint, it is not clear whether the object of a process claim is achieved if the outcome is not cited. Regarding many process claims in the patents which do not cite the outcome, this will not be applied to the instant application since each patent application is considered and examined according to its own merits.

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Conclusion

14. No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a).

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Chih-Min Kam whose telephone number is (571) 272-0948. The examiner can normally be reached on 8.00-4:30, Mon-Fri.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 872-9306 for regular communications and (703) 308-4227 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


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Chih-Min Kam, Ph. D. *CMK*
Patent Examiner

April 23, 2004


CHRISTOPHER S. F. LOW
SUPERVISORY PATENT EXAMINER
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